IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	MDL NO. 1203
THIS DOCUMENT RELATES TO:	
SHEILA BROWN, et al.	CIVIL ACTION NO. 99-20593
v.	
AMERICAN HOME PRODUCTS CORPORATION	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8412

Bartle, C.J. March 9, 2010

Jerry Kuehnel ("Mr. Kuehnel" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support his claim for Matrix Compensation Benefits ("Matrix Benefits").[3]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Mary A. Kuehnel, Mr. Kuehnel's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In August, 2002, claimant submitted a completed Green Form to the Trust signed by his attesting physician, Roger W. Evans, M.D., F.A.C.C., F.A.C.P. Dr. Evans is no stranger to this litigation. According to the Trust, he signed in excess of 322 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated November 29, 2001, Dr. Evans attested in Part II of Mr. Kuehnel's Green Form that claimant suffered from severe aortic regurgitation and had surgery to repair or replace his aortic and/or mitral valve(s) following the

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3. (...continued)
contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

use of Pondimin® and/or Redux™.[4] Based on such findings, claimant would be entitled to Matrix A-1, Level III benefits in the amount of $719,285.[5]

In the report of the reinterpretation of claimant's echocardiogram, Dr. Evans observed that "[t]here is some thickening of the aortic leaflets." Dr. Evans, however, attested that claimant did not suffer from congenital aortic valve abnormalities, including a unicuspid, bicuspid, or quadricuspid aortic valve, or a ventricular septal defect associated with aortic regurgitation. Under the Settlement Agreement, the presence of one of these congenital aortic valve abnormalities requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)i)a). As the Trust does not contest Mr. Kuehnel's entitlement to Level III benefits, the only issue before us is whether claimant is entitled to payment on Matrix A-1 or Matrix B-1.

In September, 2003, the Trust forwarded the claim for review by Craig M. Oliner, M.D., one of its auditing cardiologists. In audit, Dr. Oliner concluded that claimant had

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4. Dr. Evans also attested that Mr. Kuehnel suffered from an abnormal left ventricular dimension and a reduced ejection fraction in the range of 30% to 34%. These conditions, however, are not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level III benefits for damage to the aortic valve if he or she suffers from "left sided valvular heart disease requiring ... [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." See Settlement Agreement § IV.B.2.c.(3)(a).

a bicuspid valve and that there was no reasonable medical basis for the attesting physician's finding that claimant did not have congenital aortic valve abnormalities. In support of this finding, Dr. Oliner explained that:

> The [aortic valve] is clearly bicuspid, with parallel leaflet opening, and leaflet thickening. This is best seen on the parasternal short axis view. There may be [aortic valve] prolapse, as evidenced by a bright density in the [left ventricular] outflow tract, although this is not certain. The bright density could represent the raphe of a bicuspid valve.

Based on Dr. Oliner's diagnosis of a bicuspid aortic valve, the Trust issued a post-audit determination that Mr. Kuehnel was entitled only to Matrix B-1, Level III benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[6] In contest, claimant submitted a supplemental affidavit of Dr. Evans, who, after again reviewing claimant's echocardiogram and other documents, confirmed his prior finding that claimant did not have a bicuspid aortic valve. Claimant also submitted affidavits from a second cardiologist, Gregory R. Boxberger, M.D., F.A.C.C., and a pathologist, Terrance A. Bruner, M.D. In his affidavit, Dr. Boxberger stated that he reviewed claimant's

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6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Mr. Kuehnel's claim.

echocardiogram and determined that "claimant did not have a bicuspid aortic valve." In his affidavit, Dr. Bruner stated that he "did not find any definite evidence of a bicuspid aortic valve in the tissue" provided after "examin[ing] three portions of aortic heart valve tissue which w[ere] removed during claimant's aortic valve replacement surgery of 12/13/01."[7] Claimant also argued that: (1) the auditing cardiologist did not understand the difference between his personal opinion and the reasonable medical basis standard; and (2) no other healthcare provider has "alluded to, mentioned or diagnosed" claimant with a bicuspid aortic valve.

The Trust then issued a final post-audit determination, again determining that Mr. Kuehnel was only entitled to Matrix B-1, Level III benefits. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Mr. Kuehnel's claim should be paid. On June 16, 2004, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 3618 (June 16, 2004).

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7. Dr. Bruner attached to his affidavit a copy of his pathology report from claimant's December 13, 2001 aortic valve replacement surgery.

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on August 2, 2004. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[8] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met his burden in proving that there is a reasonable medical basis for the attesting physician's finding that he did not have congenital aortic valve abnormalities. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination

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8. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of his claim, Mr. Kuehnel reasserts the arguments he made in contest. Mr. Kuehnel also contends that the concept of inter-reader variability accounts for the difference between the opinions of the attesting physician and Mr. Kuehnel's experts and the opinion of the auditing cardiologist.

In response, the Trust avers that the disagreement between claimant's attesting physician and the auditing cardiologist cannot be attributed to inter-reader variability and that claimant "fails to cite to any literature that would suggest significant, if any, inter-reader variability in connection with the diagnosis of a bicuspid aortic valve." The Trust also argues that Dr. Bruner's pathology report actually supports a finding of bicuspid aortic valve because Dr. Bruner noted measurements for only two leaflets. The Trust contends that a third leaflet would have been noted if claimant had a "normal trileaflet aortic valve." The Trust further notes that the three verified affidavits submitted by claimant fail to show a reasonable medical basis for the attesting physician's finding and that the opinions of Dr. Evans and Dr. Boxberger rely on inferences drawn from operative and pathology reports that they did not prepare. Finally, the Trust contends that Dr. Bruner's affidavit is

unreliable as it was prepared more than two years after he examined the aortic valve tissue, and because he failed to review claimant's echocardiogram.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that claimant did not have congenital aortic valve abnormalities because the echocardiogram demonstrated a bicuspid valve. In particular, Dr. Vigilante observed that:

> The aortic valve was severely abnormal. There was significant thickening of the leaflets as well as partial calcification. This was definitely a bicuspid valve. There was congenital fusion of the right and left coronary leaflets of this aortic valve. There was eccentric closing of the aortic valve classically seen in a bicuspid aortic valve. There was partial prolapse of this combined right and left coronary leaflet into the left ventricular outflow tract during diastole leading to severe aortic regurgitation.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, we disagree with claimant that the auditing cardiologist substituted his personal opinion for the reasonable medical basis standard. To the contrary, after carefully reviewing claimant's echocardiogram, the auditing cardiologist specifically found that claimant's "[aortic valve] is clearly bicuspid ...." Moreover, Dr. Vigilante's report indicates that he considered the additional affidavits submitted by claimant and determined that they were inconsistent with a review of claimant's

November 30, 2001 echocardiogram.[9] Specifically, Dr. Vigilante noted that "[t]his was definitely a bicuspid valve." Dr. Vigilante further noted that "[t]here was eccentric closing of the aortic valve classically seen in a bicuspid aortic valve." Under these circumstances, claimant has failed to prove that a reasonable medical basis supports the attesting physician's representation that claimant did not have congenital aortic valve abnormalities.[10]

Moreover, we disagree with claimant's argument that inter-reader variability accounts for the difference between the opinion of the auditing cardiologist and the opinions provided by the attesting physician and claimant's experts. Dr. Vigilante specifically found that "[e]ven taking into consideration inter-reader variability, it would be impossible for a reasonable echocardiographer not to conclude that a bicuspid aortic valve was present on the echocardiogram of November 30, 2001."

For the foregoing reasons, we conclude that claimant has not met his burden in proving that there is a reasonable medical basis for finding that he did not have congenital aortic valve abnormalities. Therefore, we will affirm the Trust's

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9. Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor's Report. See Audit Rule 34.

10. For this reason as well, we reject claimant's argument that there is a reasonable medical basis for the finding of Dr. Evans that claimant did not have congenital aortic valve abnormalities because no other healthcare provider has "alluded to, mentioned or diagnosed" claimant with a bicuspid aortic valve.

denial of Mr. Kuehnel's claim for Matrix A-1 benefits and the related derivative claim submitted by his spouse.